

## **REMARKS**

Claims 1-126 are pending in the present application. Claims 1-126 are rejected under the judicially created doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

### **The Invention**

The present invention provides novel condensation drug aerosols and methods for producing such aerosols. These condensations aerosols have little or no pyrolysis degradation products. The unique method for generating or producing such aerosols employs rapid vaporization of the drug to minimize drug degradation during the process. These vaporized drugs are subsequently condensed to form particles of a desirable particle size for inhalation. These aerosols are especially useful in the treatment of acute or chronic conditions wherein rapid onset of treatment is desirable.

### **Withdrawal of Finality of Rejection**

Applicants have requested, and hereby request, that the Examiner reconsider the finality of the rejection as premature. The Examiner has indicated that she would withdraw the finality of the rejection, and therefore Applicants are submitting an accompanying Information Disclosure Statement for the Examiner's consideration and amending the claims of the present application as set forth herein.

### **The Amendments to the Specification**

The specification has been amended, at paragraph [0209] to note a calculated thickness of a paroxetine thin layer, on a 24.5 cm<sup>2</sup> aluminum-foil solid support, of about 9.0 microns, based on an assumed drug density of 1 g/cc.

The specification has been amended, at paragraph [0211] to note a calculated thickness of a paroxetine thin layer, on a 24.5 cm<sup>2</sup> aluminum-foil solid support, of about 8.0 microns, based on an assumed drug density of 1 g/cc.

The specification has been amended, at paragraph [0212] to note a calculated thickness of a mirtazepine thin layer, on a 24.5 cm<sup>2</sup> aluminum-foil solid support, of about 7.6 microns, based on an assumed drug density of 1 g/cc.

The specification has been amended, at paragraphs [0214] to note a calculated thickness of a mirtazepine thin layer, on a 24.5 cm<sup>2</sup> aluminum-foil solid support, of about 8.4 microns, based on an assumed drug density of 1 g/cc.

The amendments to the specification at paragraphs [0209], [0211], [0212], and [0214] are the same amendments that were made with respect to the parent U.S. patent application Serial No.

10/151,626, now U.S. Patent No. 6,783,753.

It is well-established in the case law that amendatory material is not new matter where it is concerned with an inherent characteristic of an illustrative product of an invention already sufficiently identified in the original patent disclosure. (*In re Nathan, Hogg, and Schneider*, 140 USPQ 601 (CCPA, 1964); In *In re Reynolds*, 170 USPQ 94 (CCPA 1971) the CCPA cited with approval the following holding from *Technicon Instruments Corp. v. Coleman Instruments, Inc.*, 255 F. Supp. 630, 150 USPQ 227 (N.D. Ill. 1966):

By disclosing in a patent application a device that inherently performs a function, operates according to a theory, or has an advantage, a patent applicant necessarily discloses that function, theory, or advantage even though he says nothing concerning it. The application may be amended to recite the function, theory, or advantage without introducing prohibited new matter.

This principle has been endorsed by the CAFC, e.g., in *Kennecott Corp., v. Kyocera Int'l Inc.*, 835 F. 2d. 1419, 5 USPQ2d 1194 (Fed. Cir. 1987).

The amendatory material regarding the assumed density of the drugs is already stated in the specification, e.g., see paragraph [0209] which states “. . . multiplied by the density of the drug (taken to be 1 g/cm<sup>3</sup>).” Additionally, the thickness of the coating would be readily derivable by a person skilled in the art of the claimed invention by multiplying the mass of the material by its density and then dividing this by the surface area over which it is coated. As stated above information regarding the density is readily available from the specification and other recognized sources (e.g., the CRC Handbook of Chemistry and Physics, the Aldrich Chemical Catalog, etc.) and can be assumed to about 1g/cc. The drug masses and substrate areas are also disclosed in the specification. This information is all that is needed for one to calculate the thickness.

Thus, no new matter is introduced by these amendments to the specification. The Examiner is respectfully requested to enter the amendments to the specification.

### **The Amendments to the Claims**

Without prejudice to the Applicants' rights to present claims of equal scope in a timely filed continuing application, to expedite prosecution and issuance of the application, the Applicants have amended Claims 1-3 and 64-66 and cancelled Claims 4-63 and 67-124. The Applicants also have presented new Claims 125-220. The amended claims and the new claims are supported by the specification (see below for examples of such support).

<b>Claim</b>	<b>Examples of Support in the Specification</b>
Claim 1	Paragraphs 0016, 0018, 0043, 0045; Examples 2-7
Claim 2	Paragraph 0055
Claim 3	Paragraph 0055
Claim 64	Paragraphs 0016, 0018, 0043, 0045; Examples 2-7
Claim 65	Paragraph 0055
Claim 66	Paragraph 0055
Claim 125	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0043
Claim 126	Paragraph 0043
Claim 127	As recited above for Claim 125
Claim 128	Paragraph 0018
Claim 129	Paragraph 0018
Claim 130	Paragraph 0186
Claim 131- Claim 151	Paragraph 0016
Claim 152	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0043
Claim 153	Paragraph 0043
Claim 154	As recited above for Claim 152
Claim 155	Paragraph 0018
Claim 156	Paragraph 0018
Claim 157	Paragraph 0186
Claim 158- Claim 178	Paragraph 0016, 0045
Claim 179- Claim 199	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0016, 0018, 0043, 0045
Claim 200- Claim 220	Paragraphs 0001 [incorporates by reference U.S. provisional application Ser. No. 60/317,479 (see, e.g., page 30, lines 25-27)], 0016, 0018, 0043, 0045

The amendments to the claims do not introduce new matter. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter the amendments to the claims and allow all amended claims.

### **Double Patenting**

Claims 1-126 were provisionally rejected under the judicially created doctrine of obviousness-type double patent as being unpatentable over claims of copending Application No. 10/718,982 as these claims are “either anticipated by, or would have been obvious over, the reference claims.” Office Action at 2-3.

Applicants have filed with this response a Terminal Disclaimer with regard to copending Application No. 10/718,982. Applicants believe that this addresses the Examiner’s concerns and respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the

application in view of these actions and remarks.

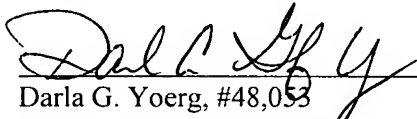
### Conclusion

The Applicants appreciate the Examiner's careful and thorough review of the application and submit that the Examiner's concerns have been addressed by the amendments and remarks above. The Applicants accordingly request the Examiner to withdraw all rejections and allow the application. In the event the Examiner believes a telephonic discussion would expedite allowance or help to resolve outstanding issues, prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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